Please add the following new claim:

41. An oral dosage form, comprising active agents consisting essentially of:
(A) at least one opioid agonist selected from the group consisting of morphine, hydromorphine, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine and pharmaceutically acceptable salts thereof,
(B) acetaminophen, and
(C) at least one opioid antagonist.

REMARKS

Reconsideration of the present application as amended is respectfully requested. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "**Version With Markings To Show Changes Made**."

I. Status of the Claims.

Claims 1, 3, 8-27, 29-32 and 35-41 are pending. Claims 1, 3, 9, 10, 12-18 and 32 have been amended. Claims 6, 7, 28 and 34 have been cancelled. Claim 41 has been added. Support for the amendments and new claims is found throughout the specification and in the claims as originally filed. It is respectfully submitted that no new matter has been added by virtue of this amendment.

II. Rejections under 35 U.S.C. § 103(a)

Claims 1, 3, 6, 8-32 and 34-40 were rejected under 35 U.S.C. 103(a) on the grounds of being obvious over the Crain reference in view of either the Hynes reference, the Raffa reference or the Dudzinski reference, further in view of the Oshlack reference. Also, claim 7 was rejected on the grounds of being obvious over the preceding combination of references further in view of the Gauthier reference.

Claims 1, 3, 6, 8-10, 12-18, 21-26, 32, 34, and 36 were further rejected under 35 U.S.C. 103(a) as being unpatentable over the Gordon reference in view of either the Hynes reference, the Raffa reference, or the Dudzinski reference, further in view of the Oshlack reference. Also, claim 7 was rejected on the grounds of being obvious over the preceding combination of references further in view of the Gauthier reference.

Although Applicants do not agree with these rejections, in order to expedite allowance of the claims, independent claim 1 has been amended, in pertinent part, to recite "[a]n oral dosage form comprising active agents *consisting essentially of* (A) at least one opioid agonist selected from the group consisting of morphine, hydromorphine, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine and pharmaceutically acceptable salts thereof, (B) acetaminophen, and (C) at least one opioid antagonist...";

It is respectfully submitted that none of the combination of references cited by the Examiner teach or suggest the presently claimed invention.

The Hynes reference is directed to compositions comprising fluoxetine or norfluoxetine in combination with codeine and optionally with aspirin or acetaminophen. The Hynes reference does not teach or suggest pharmaceutical compositions which do not include fluoxetine or norfluoxetine. The Examiner is directed to amended claim 1 and new claim 41 which recite "[a]n oral dosage form comprising active agents *consisting essentially of....*" Thus, the present claims exclude fluoxetine and norfluoxetine and the Examiner is requested to remove the rejections based on the Hynes reference in combination with the Oshlack reference and either the Crain or Gordon references, as well as the preceding references in combination with the Gauthier reference.

The Raffa reference is directed to compositions comprising tramadol and acetaminophen. The Raffa reference does not teach or suggest pharmaceutical compositions which do not include tramadol. The Examiner is directed to amended claim 1 and new claim 41 which recite "[a]n oral dosage form comprising active agents consisting essentially of (A) at least one opioid agonist *selected from the group consisting of morphine, hydromorphine, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine and pharmaceutically acceptable salts thereof....*" Thus, the present claims exclude tramadol and

the Examiner is requested to remove the rejections based on the Raffa reference in combination with the Oshlack reference and either the Crain or Gordon references, as well as the preceding references in combination with the Gauthier reference.

The Dudzinski reference is directed to compositions comprising nalbuphine and acetaminophen. The Dudzinski reference does not teach or suggest pharmaceutical compositions which do not include nalbuphine. The Examiner is directed to amended claim 1 and new claim 41 which recite "[a]n oral dosage form comprising active agents consisting essentially of (A) at least one opioid agonist *selected from the group consisting of morphine, hydromorphine, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine and pharmaceutically acceptable salts thereof ....*" Thus, the present claims exclude nalbuphine and the Examiner is requested to remove the rejections based on the Dudzinski reference in combination with the Oshlack reference and either the Crain or Gordon references, as well as the preceding references in combination with the Gauthier reference.

III. Double Patenting Rejection of Claims 1-36.

In the Office Action, the Examiner provisionally rejected claims 1-36 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent No. 6,277,384 and claims 1-36 of copending Application No. 09/503,020.

In response, it is submitted that Applicants will consider the filing of Terminal Disclaimers to obviate the double-patenting rejections upon indication from the Examiner that the claims are otherwise allowable.

IV. Conclusion

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "**Version With Markings To Show Changes Made**."

It is now believed that the above-referenced rejections and objections have been obviated and it is respectfully requested that the rejections and objections be withdrawn. It is believed that all claims are now in condition for allowance.

According to currently recommended Patent Office policy the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

An early and favorable action is earnestly solicited.

Respectfully submitted,
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Version With Markings To Show Changes Made

IN THE CLAIMS

The claims has been amended as follows:

1. (Thrice Amended) An oral dosage form, comprising active agents consisting essentially of:

(A) at least one [an] opioid agonist selected from the group consisting of morphine, hydromorphine, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine and pharmaceutically acceptable salts thereof,[;]

(B) acetaminophen,[;] and

(C) at least one [an] opioid antagonist; said dosage form further comprising [and

(D)] a sustained release carrier which causes said opioid agonist to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.

3. (Amended) The oral dosage form of claim 1, wherein the opioid agonist is hydrocodone or a pharmaceutically acceptable salt thereof and the antagonist is naltrexone or a pharmaceutically acceptable salt thereof .

9. (Amended) The oral dosage form of claim 6, wherein said opioid antagonist is selected from the group consisting of naltrexone, naloxone, nalmephene, cyclazocine, levallorphan, pharmaceutically acceptable salts thereof and mixtures thereof.

10. (Amended) The oral dosage form of claim 6, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof.

12. (Twice Amended) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is oxycodone or a pharmaceutically acceptable salt thereof.

13. (Twice Amended) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is codeine or a pharmaceutically acceptable salt thereof.

14. (Twice Amended) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is hydromorphone or a pharmaceutically acceptable salt thereof.

15. (Twice Amended) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is levorphanol or a pharmaceutically acceptable salt thereof.

16. (Twice Amended) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is meperidine or a pharmaceutically acceptable salt thereof.

17. (Twice Amended) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is methadone or a pharmaceutically acceptable salt thereof.

18. (Twice Amended) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is morphine or a pharmaceutically acceptable salt thereof.

29. (Amended) The oral dosage form of claim 28, wherein said opioid antagonist is selected from the group consisting of naltrexone, naloxone, nalmephene, cyclazocine, levallorphan, pharmaceutically acceptable salts thereof and mixtures thereof.

32. (Thrice Amended) A method of treating pain, comprising administering an oral dosage form according to claim 1 orally to a human patient [which contains an opioid agonist and acetaminophen] in an analgesically effective amount [amounts which render the dosage form analgesically effective when orally administered, the oral dosage form further including an opioid antagonist and a sustained release carrier which causes said opioid agonist to be released over a time period of about 8 to about 24 hours when orally administered to a human patient].

The following claim has been added:

41. An oral dosage form, comprising active agents consisting essentially of:
(A) at least one opioid agonist selected from the group consisting of morphine, hydromorphine, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine and pharmaceutically acceptable salts thereof,
(B) acetaminophen, and
(C) at least one opioid antagonist.